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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,831	04/04/2002	Nathan W Levin	BET-105	5604
23520	7590	04/17/2006	EXAMINER	
MAURICE M KLEE 1951 BURR STREET FAIRFIELD, CT 06824			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,831

Applicant(s)

LEVIN ET AL.

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 21-33 and 40 is/are allowed.
- 6) ☒ Claim(s) 12-20 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34-39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not recite an invention that produces a useful, concrete, and tangible result. Claims 34, 35, 36, 37, 38, and 39 merely recite an equation to calculate a volume or a constant. See step j of claim 1, step iii of claim 2, and step v of claim 4. The claims lack a recitation of a practical application for the equations. See MPEP 2106.

Claim Rejections - 35 USC § 112

Claims 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-20 recite a method of controlling a dialysis procedure where the flowing of dialysis fluid is capable of causing accumulation of ultrafiltrate. It cannot be determined from the claim whether the method includes accumulation of ultrafiltrate or flowing that merely is capable of accumulating ultrafiltrate, but no ultrafiltrate is accumulated. The method steps should clearly recite whether ultrafiltrate is accumulated or not.

Allowable Subject Matter

Claims 1-11, 21-33 and 40 are allowed.

Reasons For Allowance

Claims 1-11, 21-33 and 40 are allowed because the recited combination of steps or elements of a method and apparatus for determining the volume of a patient's peritoneal cavity using bioimpedance with measuring electrodes in place on a patient and a method and apparatus for controlling continuous dialysis fluid flow through a patient's peritoneal cavity using volume determined by bioimpedance measurements directed at the peritoneal cavity is not found nor fairly taught in the prior art of record, as argued by applicant and agreed to by examiner. In claim 28 controlling the means for continuously flowing fluid based on volume determined by bioimpedance measurement directed at the peritoneal cavity where the bioimpedance measurement directed at the peritoneal cavity is accomplished by the second means for determining volume is not found in the prior art of record.

Re claims 21 and 28 the means for determining the volume of fluid in the peritoneal cavity is construed to include the program that calculates volume of fluid in the peritoneal cavity.

Response to Arguments

Applicant argues that the calculation recited in the claims is concerned with a useful, concrete, and tangible result, i.e., the volume of fluid in the peritoneal cavity. Applicant also argues that the claims recite a calculation to determine a volume or a constant, which are a useful, concrete, and tangible result. The examiner does not agree that a useful, concrete, and

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tangible result is recited in the claims because the claims do not recite a practical application of the calculated volume or constant. The claims do not recite the use of the final calculated value of volume or constant in a practical application and therefore are not statutory claims. The claims merely recite instructions on how to calculate a volume and a constant using a mathematical formula.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
13 April 2006


MICHAEL J. HAYES
PRIMARY EXAMINER